REMARKS

Claims 1-32 are currently pending in this application, with claims 6-21 withdrawn from consideration.

REJECTIONS UNDER § 102

Applicants respectfully submit that claims 1, 2, 24, and 32 are not anticipated under § 102(e) by U.S. Patent No. 6,540,670 (Hirata et al.). Independent claim 1 recites "a plurality of tube wall bending indicators located at least on or within the catheter wall." These tube wall bending indicators "provide an indication of tube wall bending to indicate the orientation of the reference portion of the catheter." An example of this feature is demonstrated in the catheter according to the embodiment shown in FIGS. 5 and 6. The catheter 1 has eight wall bending indicators 13 within the catheter wall 7.[1] In this embodiment, tube wall bending indicators 13 are strain gauges which undergo change in electrical resistance when subjected to tensile or compressive stress. Output from the strain gauges can be used to determine the orientation of the catheter.

Hirata contains no description of any component that could be considered "a plurality of tube wall bending indicators located at least on or within the catheter wall." *Hirata* describes an endoscope system in which an elongated insertion portion has a bending portion formed from a hydropneumatic actuator.[2] The hydropneumatic actuator uses hydropneumatic pressure to bend the bending portions so that the operator can have "excellent controllability" of the endoscope system.[3] For example, in the embodiment shown in FIG. 1 of *Hirata*, the "insertion portion 8 [of the endoscope] has a long flexible tube portion 9 having flexibility, a bending portion 10 coupled to the distal end portion of the flexible tube portion 9."[4] After describing the various components of the bending portion 10 of the endoscope body and their arrangement,[5] *Hirata* explains (referring to FIGS. 1-3):

> "With this arrangement, a hydropneumatic actuator 19 is obtained, which is designed to bend the bending portion 10 by selectively supplying air to the pressurization chambers 15 of the four arcuated lumens 13*b*, 13*c*, 13*d*, and 13*e* of the multi-lumen tube 13. In this

1. Specification, at ¶ [0024]
2. see *Hirata*, e.g., at col. 1, lns. 10-15
3. see *Hirata*, e.g., at col. 2, lns. 40-56
4. see *Hirata*, e.g., at col. 12, lns. 1-3
5. see *Hirata*, e.g., at col. 12, lns. 12-56

> embodiment, the pressurization chambers 15 in the four arcuated lumens 13*b*, 13*c*, 13*d*, and 13*e* are set to correspond to four bending directions, i.e., the left and right directions and the upward and downward directions." [6] (emphasis added)

In another example, in the embodiment shown in FIG. 30, the endoscope system is operated with a joystick. *Hirata* explains this embodiment as follows:

> "In this embodiment, when the operator operates a joystick 127 of an operating portion 118 in a desired bending direction, the syringe unit 151 in the bending direction corresponding to the operation of the joystick 127 operates. The air sent from the syringe 155 of the syringe unit 151 is sent to the pressurization chamber 15 of the hydropneumatic actuator 109 of the bending portion 106, thereby bending the bending portion 106." [7] (emphasis added)

Thus, the "bending portion" in the *Hirata* endoscope contains a bending mechanism that may be controlled by the operator. This "bending portion," however, does not contain any "tube wall bending indicators" that provide information indicating orientation, as recited in claim 1. For at least these reasons, Applicants respectfully contend that claims 1, 2, 24, and 32 are not anticipated by *Hirata*, and Applicants request the allowance of these claims.

REJECTIONS UNDER § 103

Applicants respectfully contend that claims 3, 4, 22, and 23 are patentable over *Hirata* in view of U.S. Patent No. 4,690,673 (Bloomquist).

A. The Combination of *Hirata* and *Bloomquist* is Improper

The Office Action suggests the modification of *Hirata* "by making a tube wall having a plurality of strain gauges as taught by Bloomquist" to arrive at the inventions of claims 3, 4, 22, and 23. Applicants respectfully submit that there is no basis for combining *Hirata* with *Bloomquist* in this manner.

Bloomquist describes an intravenous (IV) infusion device for infusing fluids to a patient through an IV tube.[8] The infusion device functions as a peristaltic pump that squeezes the IV

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6. *Hirata*, at col. 12, lns. 57-65
7. *Hirata*, at col. 34, lns. 17-24
8. see *Bloomquist*, e.g., Abstract, and col. 3, lns. 28-31

tubing to propel the fluid.[9] In IV infusion systems, monitoring fluid pressure in the IV line is important for safe operation during patient infusions.[10] As such, the *Bloomquist* device uses strain gauges to determine fluid pressure in the IV tubing as the fluid is being pumped.[11] The operation of the infusion device is controlled by readings from these strain gauges.[12]

As shown in FIG. 6 of *Bloomquist*, adapting a strain gauge for use in monitoring fluid pressures in an IV tubing is not a simple matter. In the *Bloomquist* device, the strain gauge works in cooperation with a gauge assembly 44, which has a mounting block 70 and a cantilevered strain beam 68 mounted thereon.[13] Also involved in the operation of gauge assembly 44 are a travel limiter 72 extending from mounting block 70, a protective extension 74 mounted on the opposite side of cantilevered strain beam 68, a pressure transmitting member 76 fixed to strain beam 68 to physically connect the end of cantilevered strain beam 68 with pumping section 18, and an electrical junction block 78 connected with cantilevered strain beam 68 for providing the electrical circuitry from the strain gauge.[14]

Unlike the *Bloomquist* infusion device, the endoscope system of *Hirata* is not designed for intravenous infusions, and as such, it does not use IV tubing. Therefore, *Hirata* has no need for the strain gauge of *Bloomquist* to monitor fluid pressures in an IV tubing. Furthermore, neither the Office Action nor the cited references suggests how the strain gauge of *Bloomquist*, which is designed for determining fluid pressure in an IV tubing, could be adapted for use in determining tube wall bending. As demonstrated by the numerous accessory components associated with the operation of the strain gauge in the *Bloomquist* device, adapting the strain gauge for use in fluid pressure monitoring was not a simple matter. Likewise, it would not be a simple matter to adapt such a strain gauge to work in the limited confines of the "bending portion" in the *Hirata* endoscope.

Because there is no reason for using the strain gauge of *Bloomquist* in the endoscope system of *Hirata*, this combination suggested by the Office Action is improper. For at least these reasons, Applicants respectfully submit that claims 3, 4, 22, and 23 are patentable over

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9. see *Bloomquist*, e.g., Abstract, and col. 3, lns. 32-37
10. see *Bloomquist*, col. 2, lns. 14-18
11. see *Bloomquist*, e.g., Abstract, and col. 7, lns. 65-67
12. see *Bloomquist*, e.g., Abstract, and col. 7, ln. 67 – col. 8, ln. 9
13. see *Bloomquist*, col. 6, lns. 21-23
14. see *Bloomquist*, col. 6, lns. 29-45

Hirata in view of *Bloomquist*, and Applicants request the allowance of these claims.

B. The Combination of *Hirata* with *Bloomquist* Does Not Include All Required Elements

Claims 3, 4, 22, and 23 depend from independent claim 1, which recites "a plurality of tube wall bending indicators located at least on or within the catheter wall." To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See* MPEP § 2143.03. Even if *Hirata* and *Bloomquist* could be properly combined, the combination would not include "a plurality of tube wall bending indicators located at least on or within the catheter wall."

As explained above, this feature is absent in *Hirata*. *Bloomquist* does not contain anything that cures this deficiency of *Hirata*. Therefore, even if *Hirata* and *Bloomquist* could properly be combined in the manner suggested by the Office Action, the combination would still not include all the elements of claims 3, 4, 22, and 23. For at least these reasons, Applicants respectfully submit that claims 3, 4, 22, and 23 are patentable over *Hirata* in view of *Bloomquist*, and request the allowance of these claims.

CONCLUSION

Applicants respectfully submit that the present application is in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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